



STATE OF WASHINGTON
DEPARTMENT OF HEALTH
Olympia, Washington 98504

WASHINGTON STATE BOARD OF PHARMACY
MEETING MINUTES
December 11, 2008

Department of Health Kent Offices
Marketing Center Creekside Three
at CenterPoint
20435 72nd Ave S, Suite 200
Kent, Washington 98032

CONVENE

Chair Rebecca Hille called the meeting to order at 9:01 a.m., December 11, 2008.

Board Members present:

Rebecca Hille, BA-Public Member
Albert Lingii, RPh
Dan Connolly, RPh
Rosemarie Duffy, RN, MA, MSN, Public Member

George Roe, RPh
Gary Harris, RPh Vice-Chair
Vandana Slatter, PharmD

Staff Member present:

Gail Yu, AAG (Sitting in for Joyce Roper)

Steve Saxe, Rph, Executive Director (Acting)
Lisa Hodgson, Executive Manager
Grant Chester, Chief Investigator
Stan Jeppesen, Investigator
Cathy Williams, Pharmacist Consultant
Tim Fuller, Pharmacist Consultant
Doreen Beebe, Program Manager
Leann George, Program Support

Guest / Presenters

Dean Webb, Director of Pharmacy –
Department of Corrections
Alice Cooper, P.E.
Cheri Grasso, Hazardous Waste Management
Program in King County

Mission Statement

The mission of the Board of Pharmacy is to achieve the highest standards in the practice of pharmacy and promote public health and safety and to effectively communicate with the Governor, Legislature, the Department of Health, the public and profession.

Vision Statement

The Washington State Board of Pharmacy leads in creating a climate for the patient-focused practice of pharmacy.

We support and encourage our pharmacists to inform, educate, consult, manage drug therapy and provide products as an integral part of an accessible, quality-based health care system.

As a result, the citizens of Washington State:

- Are well informed about medications;
- Take responsibility for their health;
- Utilize pharmacists and other health care providers appropriately; and
- Experience the highest level of health and wellness

CONSENT AGENDA

- 1.1** Pharmacist License Application Approval.
- 1.2** Pharmacy & Other Firm Application Approval.
 - New Firm Licenses issued October 10 thru December 4 – No closures to report
- 1.3** Pharmacy Technician Application Approval.
- 1.4** Pharmacy Tech Training Program Approval.
 - Bi-Mart Pharmacy #610 in Oregon – submitted by applicant Jennifer Ackman
 - Salt Lake Tooele Applied Technology College – submitted by applicant Paul Egleston
 - Pima Medical Institute – submitted by applicant Kevin Harmon
 - Walgreens Pharmacy #05185 in Boise ID – submitted by applicant Emily Lytle
 - Foreign Graduate Alissa Dantes-Asuncion – Bachelor of Science in Pharmacy – Centro Escolar University – Philippines
- 1.5** Collaborative Drug Therapy Agreement Acceptance.
 - 1. Auburn Regional Med Center – Anticoagulation – Various Pharmacist
 - 2. Auburn Regional Med Center – Intravenous to Oral Conversion – Various Pharmacist
 - 3. Auburn Regional Med Center – Total Parenteral Nutrition – Various Pharmacist
 - 4. Auburn Regional Med Center – Renal Dose Adjustment– Various Pharmacist
 - 5. Pacific Medical Centers Pharmacy – Refills – Various Pharmacist
 - 6. Bartells #58 – Anti Malaria – Marla Gonn and Stephen Long
 - 7. Bartells #58 – Epi-Pen – Marla Gonn and Stephen Long
 - 8. Bartells #58 – Motion Sickness – Marla Gonn and Stephen Long
 - 9. Bartells #58 – Altitude Sickness – Marla Gonn and Stephen Long
 - 10. Bartells #58 – Travelers’ Diarrhea – Marla Gonn and Stephen Long
- 1.8** Board Minute Approval October 31, 2008

Items listed under the consent agenda are considered to be routine agency matters and will be approved by a single motion of the Board without separate discussion. If separate discussion is desired, that item will be removed from the consent agenda and placed on the regular business agenda. **Items 1.1, 1.3, 1.6, and 1.7** have been **deleted** from the agenda

MOTION: George Roe moved that the board approve items 1.2, 1.4, 1.5, and 1.8. Gary Harris second.
MOTION CARRIED: 6-0.

Special Announcements:

Rebecca Hille presented board member George Roe with letter from Governor and plaque in recognition and appreciation for his dedicated service to the Board and the people of Washington State. George Roe was appointed to the board on February 7, 2001 and has served two consecutive 4 year terms.

REPORTS

Board Member

Al Lingii reported:

- He spent five days in Orlando Florida at the American Society Health Systems Pharmacy (ASHP) Meeting. During the course of that meeting Al met with group of ASHP members that are also Board of Pharmacy members from various states. He was able to identify those particular states with contemporary regulations with regard to hospital pharmacy practice and institutional practice.
- Received a report from National Association of Boards of Pharmacy regarding some of the issues they are attempting to identify in regards to pharmacy practice and their goals specifically with hospital pharmacies.
- NABP is looking to establish accreditation for retail pharmacies.
- Mr. Linggi plans to collaborate with members of ASHP on hospital pharmacy rules and regulations.

George Roe reported:

The Sanction Committee turned in their recommendations to the Secretary of Health. The members of the committee received a letter from the Secretary of Health with a few questions regarding the recommendations. November 26, 2008 the Sanctions Committee had a meeting to discuss these questions in the letter.

Rebecca Hille reported:

- She attended the Boards and Commissions meeting November 7, 2008. The Board of Pharmacy had the most attendance at the meeting. The meeting began with greetings from Steve Saxe. Mary Selecky spoke about the state of Washington's health and Dr. Hayes spoke on troubling trends in Washington State. There was small group work in the afternoon which made it possible to get to know members of other boards and commissions.
- She attended the Spokane Pharmacy Association Annual Banquet in November.
 - Rebecca also attended their Technician Law Update where William Fassett gave a seminar.

Executive Director

Steve Saxe reported:

- Steve attended the Tribal Leader Summit along with other local and state health department staff. He participated on a work group looking at regulatory oversight of health facilities or

services provided on by tribal organizations on tribal land. We are considering a memorandum of understanding to provide inspections and investigation activities for the tribal leadership. This could also include pharmacy so he will keep the board updated.

- The department will follow up on the November 7th boards and commission meeting held to further discuss the feedback regarding operating agreements and performance measures.
- There was a newspaper series on methicillin-resistant staphylococcus aureus (**MRSA**). The department is working with local health departments on this issue. We will also finalize the hospital operating rules which include changes in the regulations around infection control programs.
- This Legislative session the department will continue the weekly legislative update calls with a representative from each board and commission.
- Steve is continuing along with Karen Jensen, Assistant Secretary, to meet with all boards and commissions to give an overview about the re organization within the Department of Health.
- Steve discussed the budget situation and the significant deficit projected in state revenue. All state agencies, boards, commissions and higher education have been asked to look at ways to reduce spending. Especially in programs funded by the general state funds. Because of the need to reduce costs we will not be able to move forward with the Prescription Monitoring Program at this time.

Assistant Attorney General

Gail Yu reported:

Assistant Attorney General, Gail Yu introduced herself. She was standing in for Joyce Roper.

Consultant Pharmacists

Tim Fuller reported:

- He participated on another statewide exercise with the Strategic National Stockpile. It was a pandemic flu exercise. They worked two shifts of people which would likely need to happen in this situation. There is always something to learn on these exercises.
- Tim spent a number of hours with Joyce Roper and with the other plaintiff's from the Storman's case.

Cathy Williams reported:

Washington Patient Safety Coalition Medication Reconciliation Practice secured a free full blown marketing plan. They will be meeting the beginning of next month to see how to proceed with their Carry & Share Project. The meeting with the Coalition's Steering Committee will be to decide on how to proceed with implementing the marketing plan.

Chief Investigator

Grant Chester reported:

- Pharmacy extern Grady Clapp helped compile an overview of the "Harold Rogers Prescription Monitoring Program FY 2008." The results of his research suggest that the most successful applicants attend conferences sponsored by the Nation Association of State Controlled Substance Authorities, Alliance of States with Prescription Monitoring Programs and the Department of Justice.
- Our next extern Joseph Fernandez will start his rotation January 2009.

- Jim Doll and Grant Chester participated in the Department of Health Emergency Exercise “Pandemonium” in November.
- Jim Doll continues to work with Doreen Beebe on the correctional facilities rules.
- In November there were 108 inspections and 49 investigations.

PRESENTATIONS

Pharmaceutical Household

Pharmacist Investigator Stan Jeppesen was accompanied by Alice Cooper, P.E. and Cheri Grasso from the local Hazardous Waste Management Program in King County to present an overview and update the board on the Pharmaceutical Household: A Return Mechanism project (PH:ARM project).

Overview of the PH:ARM Pilot Program

- The public safety regarding medications was the primary reasons for the Board of Pharmacy to approve the PH:ARM program.
 - A 395% increase of accidental poisonings from 1990 to 2006.
 - Prescription drugs were being abused for non medical reasons.
 - These medicines were found in 80% of 139 streams that were sampled in 30 states.
 - Septic systems, wastewater and sewage treatment do not eliminate most medicines.
- The program began in 2006.
 - Group Health started the program in November 2006
 - Bartell Drug Company started in June 2008.
 - Two boarding homes began the program in November 2008.
- Security.
 - Collection in clinical and retail pharmacies.
 - Storage is secure and consolidated at pharmacy warehouse.
 - Buckets are shipped and tracked.
 - Witnessed incineration.
- PH:ARM Pilot Program Goals.
 - Work with community partners to develop a medication disposal system.
 1. Secure.
 2. Affordable.
 3. Reproducible.
 4. Sustainable.
 5. Meets all regulatory requirements.
 6. Easy for our patients to use.
 - Reduce medications in the home posing a risk of unintentional poisoning, overdose or abuse.
 - Model a program that can serve all of Washington.
 - Create a model for other states.
- Board Concerns
 - Availability to the public.
 - Open to audit and review.
 - Operated by licensed personnel and facilities.
 - Provide secure collection with confirmation of tracking and destruction.

The PH:ARM pilot program has met all of these concerns.

- Regulatory Issues
 - State Boards of Pharmacy.
 - ✓ Protocol review and approval.
 - Drug Enforcement Administration.
 - ✓ Controlled substance.
 - Department of Transportation and United States Postal Services.
 - ✓ Waivers or approvals for some methods or materials.
 - United States Environmental Protection Agency.
 - ✓ Keeping business and household wastes separate.
- What has been learned during the PH:ARM Pilot Program.
 - Secure containers work.
 - Security tracking works, there has been no lost or diverted material.
 - Costs are high for screening after collection.
 - Pre-screening can significantly reduce programs cost. (If pre-screening time not counted)
- Data Collected
 - Preliminary Study
 - ✓ 94.2% if material met acceptance criteria.
 - ✓ 1.5% demonstrated the need to screen.

Drug categories Collected:

	<u>Bartell Drugs (710lbs)</u>	<u>Group Health Cooperative(1,951)</u>
Legend Drugs	55%	53%
Over The Counter	26%	19%
Nutraceutical	11%	14%
Not PHARM	7%	9%
Unknown drugs	1%	5%

- Our next step.
 - Seeking endorsements
 - Talking with:
 - ✓ Legislators
 - ✓ Pharmaceutical manufacturers and producers.
 - Proposed legislation would change relevant Washington regulations to allow for the take back program
 - Successful passage in 2009.

Prescription Monitoring Program (PMP)

The board heard an update on the PMP program during Steve Saxe's reports. The Prescription Monitoring Program will not be moving forward because of the economic crisis within all of the state departments. The board members were really disappointed to hear this news. They feel there is a real need to have this program.

Telepharmacy

Tim Fuller provided brief background on a proposal by King County Public Health Community Health Services to utilize telepharmacy services. Tim introduced Dean Webb, Director of Pharmacy who presented the proposal and answered questions.

King County is also experiencing a budget crisis. Funding has been lost for many of King County's programs. The funding has been cut for our North Public Health Clinic Pharmacy. We have come up with some money to put into a telepharmacy system with the board's approval. Having a 52% population of uninsured patients in this area we would like to have the ability to provide prescriptions for those who don't have any other alternatives.

Highlights:

- If possible the provider will come to the remote pharmacy.
- Continuous Quality Program (CQI) process will be review quarterly by the responsible pharmacist. The CQI process will have a more formal review at the state level.
- Medications that will go into that device will be prepackaged and have a barcode put on them at our downtown pharmacy warehouse. A public health courier would take them to the North Public Health Clinic to the device.
- There is a barcode on label and a barcode on the bottle to dispense out of the machine. Those are scanned. Then to verify the pharmacy technician will hold label and prescription up to video screen so pharmacist can do a visual verification.
- There are 40 to 50 new prescriptions and 40 to 50 refills being filled.
- Two pharmacy technicians in downtown, one pharmacist and pharmacy technician at the North Public Health Pharmacy, and one pharmacy technician at the warehouse.

Concerns:

- Replacing pharmacy services.
- Handling more than one prescription.
- Prepackaging medications procedure.
- Pharmacist to pharmacy technician ratio.
- Pharmacy license for the North Public Health Clinic.

The board discussed having better criteria for this type of system.

MOTION: George Roe moved that the board postpone the request to approve the use of a telepharmacy at North Public Health Clinic at the January 22, 2009 meeting for more information and discussion. Rosemarie Duffy second. **MOTION CARRIED:** 6-0.

DISCUSSION

Rules Workload Update

Doreen Beebe reviewed the rules workload matrix and answered questions.

1. *Correction Pharmacies* draft rule will be discussed by the board later during this meeting.
2. *Extended Care Facilities Destruction of Controlled Substances* has no updates. The board may need to review this rule again.
3. *Adding SOMA to Controlled Substance Act* CR102 is in process. Tim Fuller is waiting to see if he is going to needs a small business economic impact statement.
4. *Update Animal Control Agency and Humane Society Rules* CR101 drafting will begin in late November. We have asked the Veterinary Board of Governors for input. We also need to do additional research on federal requirements for these facilities to ensure the model policies and

procedures are appropriate for animal control agencies as well as humane societies. We do not have a lead staff member assigned to this rule.

5. *Stop renumbering refill prescription if no changes are made to the original prescription* has had no update as of October 2008. We do not have a lead staff member assigned to this rule.
6. *Telepharmacy* has had no action at this point.
7. *Update Controlled Substance Act* the CR105 packet is just about ready to be filed to the Rules Management System. We need to research changes to CFR's referenced in current rule language.
8. *Update Hospital Rules* has had no action. Al Lingii has been assigned as the champion board member. Pharmacy hospital standards will be discussed later in this meeting which will be helpful for this rule. We do not have a lead staff member assigned to this rule.
9. *Perpetual Inventory – CII's* has had no updates. This has not been started on.
10. *Update Wholesaler Rules* has been postponed until pedigree/technology issues are resolved.
11. *Impaired Pharmacist Rehabilitation* was just added last month. WRAPP asked that the board allow for unobserved urine analysis collection provided that there are safeguards to ensure that the collection is trustworthy. We will need to assign a champion board member and a lead staff member to this rule.

Doreen asked that the board make sure they feel these rules are appropriately prioritized. There was some discussion on ways to help move forward on these rules. Gary Harris mentioned that it would be nice to identify primary and secondary rules. Al Lingii suggested making target dates. Gail Yu recommends that the board members work close with the staff to work on target dates to set intermittently goals for rules.

Pharmacy Hospital Standards

At the request of the board a brief survey was conducted with the investigators to determine what sections of WAC 246-873 would need to be modified or updated to reflect current practice. Pharmacy Investigators Jim Doll provided a memorandum with all of the investigators input to assist with the discussion. Tim Fuller addressed any questions regarding the Investigators comments.

- Sterile product compounding: The "797" standards needs to be addressed and make these rules in agreement with the federal standards.
- Controlled Substance Witness Wastage: The language needs to be modified to allow another health care professional who is authorized to administer to witness wastage. Now the rule allows only another nurse to witness the wastage.
- Telepharmacy and Remote Order Verification: Develop rules in this area.
- Emergency Outpatient Prescription: Rules need to be modified to address 1989 list of exempt hospitals (WAC 246-873-060).
- Electronic order entry: Develop rules in this area.
- Electronic Records: Address the development of PYXIS and other automated drug dispensing devises.

EXECUTIVE SESSION (Closed Session)

The board convened to executive session at 11:47 a.m.

The board adjourned for closed session at 12:07 p.m. and reconvened at 1:00 p.m.

DISCUSSION cont'd

Correctional Pharmacy Standards - Draft Rules

Doreen Beebe provided the board an updated summary of the stakeholder work and answered questions, with the assistance of Pharmacy Investigator Stan Jeppesen.

- December 10, 2008 Doreen Beebe received a call from Washington State Association of Sheriffs and Police Chiefs with a concern that the language could be construed to apply to their facilities. It was suggested that the definition of correctional facilities be changed to reference specific statutes. We were concerned that simply citing specific statutes would not allow the rule to be applied to all locations that are currently licensed by the board. It was also suggested that the section 020 Applicability be changed to :

Draft Rule states: The following rules and regulations are applicable to all correctional pharmacies as defined in this chapter.

Purposed change: The following rules and regulations are applicable to all correctional facilities with correctional pharmacies as defined in this chapter.

With discussion and the input from Gail Yu the board decided to not change the language. The requested change would have placed the onerous on the facility rather than the correctional pharmacy. Rosemarie Duffy also added that the board believes the definition of correctional facility to be adequate.

- There were some issues that were raised by Joyce Roper AAG under 246-874-070.
 - 246-874-070 #1(a) (vi) Policies regarding the provision of medication to patients upon their release; and (to provide was replaced).
- Bill Spears shared his comments and concerns to this draft rule.
 - 246-874-075 #2 (b)(ii) Drugs shall be packaged using unit dose or a modified unit dose packaging system in amounts sufficient for the immediate therapeutic requirements; (until the pharmacy opens was deleted).

With consensus the board accepts the draft rule with changes made today. Doreen Beebe received the approval to move forward with the CR102.

Legislation Update

Lisa Hodgson updated the board on any pre-filled legislation. We have been provided some technical assistance on the Prescription Take Back Program and on the Tamper Resistance Program.

Delegation of Authority

Tim Fuller presented a proposal to the board to delegate authority to review and to approve collaborative drug therapy agreements to a pharmacist consultant. He shared a brief background on the reviewing of collaborative agreements.

MOTION: Rosemarie Duffy moved that the board approve to continue current collaborative agreement review process and the board delegates the authority to approve agreements to a pharmacist consultant with the amendment to continue to have a list of the agreements on the agenda. George Roe second. **MOTION CARRIED:** 6-0

Election of Officers

MOTION: George Roe nominated Gary Harris for Chair for 2009. Dan Connolly second.

MOTION: Rosemarie Duffy move that the nominations be closed and that Gary Harris will be the Chair for 2009. Dan Connolly second **MOTION CARRIED:** 6-0.

MOTION: Dan Connolly nominated Rosemarie Duffy to be Vice Chair for 2009. Vandana Slater second.

MOTION: George Roe moved that the nominations be closed and that Rosemarie Duffy be the Vice Chair for 2009. Vandana Slater second. **MOTION CARRIED:** 6-0.

The board discussed the Tuesday Meet Me Calls during legislation session. Rosemarie Duffy was selected to represent the Board of Pharmacy.

CORRESPONDENCE

The Board will discuss correspondence received.

- NABP e-News
 - November 12, 2008 – FDA Seizes Contaminated Heparin from Cincinnati
 - November 26, 2008 – FDA Opens Inspection Office in China
- ISMP medication Safety Alert – Community/Ambulatory Care Edition – November 2008
- Final Report from Sanction Schedule Committee
- NABP State News Roundup – October 2008
- ILRS/Renewal Backlog Status – November 14, 2008
- NABP Findings Underscore Dangers of Purchasing Prescription Medication online and from Foreign Sources
- NABP State News Roundup – November 2008

OPEN FORUM

Audrey Adams introduced herself as a mother she is not affiliated with any organization. She received a response back from the complaint that she filed to the Board of Pharmacy against the water district specifically the Seattle Public Utility and her water district for dispensing fluoride without a license. Mrs. Adams realized that this is not the board's jurisdiction. Her problem is that no one is taking responsibility for this situation and the damage that it is causing. She is asking the board for help to figure out whose jurisdiction or whose responsibility it is. Rosemarie Duffy suggested that she try to work on gathering citizens and inform them push on having fluoridation removed from the water.

Patrick Galler a pharmacy manager for Walmart Pharmacy in Longview. He made it clear he was not representing Walmart. While sitting at board meetings he realized that the board does not have the mandate for directing pharmacy technicians continued education (CE's) hours. Mr. Galler is taking it upon himself to get legislation drafted to give the board the mandate to direct CE hours for pharmacy technicians. He is working with Representative Ed Worcutt. They are in the drafting process. He just wanted to give the board an update. Al Lingii offered Patrick Galler some contacts from some folks from American Society Health Systems Pharmacy (ASHP). These contacts may be able to provide Mr. Galler some assistance. Dan Connolly thanked Mr. Galler for being involved.

Colin Conway introduced himself and stated he was speaking on behalf of himself. He was looking for some guidance on the definition of compounding. He asked the board if they had any thoughts on

defining some guidelines. Stan Jeppesen stated he would like to see some guidelines on this. Stan commented this is hard to get into this without a huge discussion.

Request for Approval to Receive Lists/Labels

The board was asked to make a motion to delegate a panel on this discussion.

MOTION: Rosemarie Duffy motioned that a panel be delegated for this discussion. Vandana Slatter second. **MOTION CARRIED:** 6-0.

Rebecca Hille chose Dan Connolly, George Roe and Rosemarie Duffy as the panel for this discussion.

Career Staff Unlimited a division of Sun Healthcare requested to be recognized as a professional association. They would like to receive mailing information for pharmacist to educate pharmacy professionals on career opportunities with Sun Healthcare group. **MOTION:** George Roe moved to deny the request for Career Staff Unlimited to be recognized as a professional organization because they do not meet the definition of a professional organization. Dan Connolly second. **MOTION CARRIED:** 2-0.

BUSINESS MEETING ADJOURNED

There being no further business, the board adjourned at 4:30 p.m. The Board of Pharmacy will meet again on January 22, 2009 for its regularly scheduled business meeting in Des Moines, Washington at the Marina Inn.

PRESENTATION OF AGREED ORDERS

CLOSED SESSION

Respectfully Submitted by:

Leann George, Program Support

Approved on January 22, 2009

*Gary Harris, Chair
Washington State Board of Pharmacy*

